

Attachment B



December 22, 2016

Via Online FDA FOIA Portal

Re: FOIA request for communications between the President-elect's transition team and FDA staff

Dear FOIA Officer:

I write on behalf of the Natural Resources Defense Council (NRDC) to request disclosure of records pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and applicable Food and Drug Administration (FDA) regulations at 21 C.F.R. § 20.1-20.120.

I. Description of Records Sought

Please produce records¹ in FDA's possession, custody, or control that are, include, or reflect communications between FDA staff in the Office of Foods and Veterinary Medicine (including the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine) and any member of the transition team(s) of President-elect Donald Trump and/or Vice-President-elect Mike Pence. The term "transition team(s)" includes, but is not limited to, the staff members described in the Presidential Transition Act of 1963 and all amendments, 3 U.S.C. § 102 note. These members may include, but are not limited to, Peter Thiel, Marie Meszaros, John Brooks, Andrew Bremberg, Renee Amore, Scott Gottlieb, Eric Hargan, Nina Owcharenko Schaefer, Kamran Daravi, Ed Haislmaier, Maggie Wynne, and Paula Stannard.

II. Request for a Fee Waiver

NRDC requests that FDA waive any fee it would otherwise charge for search and production of the records described above. FOIA dictates that requested records be provided without charge "if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii); *see also* 21 C.F.R. § 20.46(a). The requested disclosure would meet both of these requirements. In addition, NRDC qualifies as "a representative of the news media" entitled to a reduction of fees under FOIA. 5 U.S.C. § 552(a)(4)(A)(ii)(II); *see also* 21 C.F.R. § 20.45(a)(2).

¹ "Records" means anything denoted by the use of that word or its singular form in the text of FOIA and includes correspondence, minutes of meetings, memoranda, notes, emails, notices, facsimiles, charts, tables, presentations, orders, filings, and other writings (handwritten, typed, electronic, or otherwise produced, reproduced, or stored). This request seeks responsive records in the custody of any FDA office, including, but not limited to, FDA Headquarters offices, and specifically including FDA offices in possession of responsive records.

A. NRDC Satisfies the First Fee Waiver Requirement

The disclosure requested here would be “likely to contribute significantly to public understanding of the operations or activities of the government.” 5 U.S.C. § 552(a)(4)(A)(iii); 21 C.F.R. § 20.46(a)(1). Each of the four factors used by FDA to evaluate the first fee waiver requirement indicates that a fee waiver is appropriate for this request. *See* 21 C.F.R. § 20.46(b).

1. *Subject of the request*

The records requested here reflect communications between FDA and the President-elect’s transition team after a presidential election. The requested records thus directly concern “the operations or activities of the government.” 21 C.F.R. § 20.46(b)(1).

2. *Informative value of the information to be disclosed*

The requested records would “reveal any meaningful information about Government operations or activities that is not already public knowledge.” 21 C.F.R. § 20.46(b)(2). The public does not currently possess comprehensive information regarding the transition of power within the agency. There is more than a reasonable likelihood that these records have informative value to the public because, for example, the President-elect sent a questionnaire to Department of Energy staff asking about involvement in specific areas of research and attendance at climate-related conferences. *See* “Climate Change Conversations Are Targeted in Questionnaire to Energy Department,” Coral Davenport, *New York Times*, Dec. 9, 2016, <http://www.nytimes.com/2016/12/09/us/politics/climate-change-energy-department-donald-trump-transition.html? r=0>. There may be similar communications with FDA that would similarly have informative value to the public. *See Citizens for Responsibility & Ethics in Washington v. U.S. Dep’t of Health & Human Servs.*, 481 F. Supp. 2d 99, 109 (D.D.C. 2006).

We believe that the records requested are not currently in the public domain. Their disclosure would thus meaningfully inform public understanding with respect to the transition at FDA, as further discussed below. However, if FDA were to conclude that some of the requested records are publicly available, NRDC would like to discuss that conclusion and might agree to exclude such records from this request.

3. *Contribution to an understanding of the subject by the public is likely to result from disclosure*

Because NRDC is a “representative of the news media,” as explained in Part II.C below, that is sufficient evidence that this disclosure is likely to contribute to public understanding of its subject. 21 C.F.R. § 20.46(b)(3).

However, even if NRDC were not a media requester, NRDC’s expertise in matters concerning FDA staffing and policy, extensive communications capabilities, and proven history of dissemination of information of public interest—including information obtained from FOIA records requests—indicate that NRDC has the ability to and will use disclosed records to reach a broad audience of interested persons with any relevant and newsworthy information the

records reveal. There is a strong likelihood that disclosure of the requested records will increase public understanding of the subject matter. *See Judicial Watch, Inc. v. Rossotti*, 326 F.3d 1309, 1314 (D.C. Cir. 2003) (finding that a requester that specified multiple channels of dissemination and estimated viewership numbers demonstrated a likelihood of contributing to public understanding of government operations and activities).

NRDC intends to disseminate any newsworthy information in the released records and its analysis of such records to its member base and to the broader public, through one or more of the many communications channels referenced below. NRDC has frequently disseminated newsworthy information to the public for free, and does not intend to resell the information requested here. As NRDC's long history of incorporating information obtained through FOIA into reports, articles, and other communications illustrates, NRDC is well prepared to convey to the public any relevant information it obtains through this records request. *See* 21 C.F.R. § 20.46(b)(3).

NRDC has the ability to disseminate information collected from this FOIA request through many channels. As of June 2016, these include, but are not limited to the following:

- NRDC's website, available at <http://www.nrdc.org> (homepage at Att. 1), is updated daily and draws approximately 1.3 million page views and 510,000 unique visitors per month. The new NRDC.org launched in late March 2016 and features NRDC staff blogs, original reporting of environmental news stories, and more.
- NRDC's Activist email list includes more than 2.1 million members and online activists who receive regular communications on urgent environmental issues. (sample email at Att. 2) This information is also made available through NRDC's online Action Center at <https://www.nrdc.org/actions> (Att. 3).
- *NRDC This Week* is a weekly electronic environmental newsletter distributed by email to more than 86,700 subscribers, at <http://www.nrdc.org/newsletter> (Att. 4).
- NRDC updates and maintains several social media accounts: Facebook (565,530 followers) (Att. 5), Twitter (195,426 followers) (Att. 6), Instagram (37,868 followers) (Att. 7), YouTube (19,518 subscribers) (Att. 8), and LinkedIn (9,108 followers) (Att. 9). We also use Medium as another distribution channel for our content (1,478 followers).

NRDC issues press releases, issue papers, and reports; directs and produces movies, such as *Sonic Sea*, *Stories from the Gulf*, and *Acid Test*, narrated by Rachel McAdams, Robert Redford, and Sigourney Weaver, respectively; participates in press conferences and interviews with reporters and editorial writers; distributes content on Huffington Post (Att. 10); and has more than fifty staff members dedicated to communications work.

NRDC employees provide Congressional testimony; appear on television, radio, and web broadcasts and at conferences; and contribute to numerous national newspapers, magazines, academic journals, other periodicals, and books. A few examples are provided below:

- Research article, “The requirement to rebuild US fish stocks: Is it working?” *Marine Policy*, July 2014 (co-authored by NRDC Oceans Program Senior Scientist Lisa Suatoni and Senior Attorney Brad Sewell) (Att. 11);
- Issue brief, “The Untapped Potential of California’s Water Supply: Efficiency, Reuse, and Stormwater,” June 2014 (co-authored by NRDC Water Program Senior Attorney Kate Poole and Senior Policy Analyst Ed Osann) (Att. 12); *see also* “Saving Water in California,” *N.Y. Times*, July 9, 2014 (discussing the report’s estimates) (Att. 13);
- Article, “Waves of phony charges over new clean water safeguards,” *The Hill*, June 17, 2014 (by NRDC Executive Director Peter Lehner) (Att. 14);
- Article, “Don’t Buy the Smear of the EPA,” *L.A. Times*, June 3, 2014 (by NRDC President Frances Beinecke) (Att. 15);
- Transcript, “Conservationists Call For Quiet: The Ocean Is Too Loud!” Nat’l Pub. Radio, *All Things Considered*, July 28, 2013 (featuring NRDC Marine Mammal Protection Program Director Michael Jasny) (Att. 16);
- Testimony of David Doniger, NRDC Climate and Air Program Policy Director and Senior Attorney, before the United States House Subcommittee on Energy and Power, June 19, 2012 (Att. 17);
- Article, “Pollution Still a Hazard to U.S. Beaches,” CBS, *CBS NEWS*, July 29, 2009 (featuring former NRDC Water Program Co-Director Nancy Stoner) (Att. 18);
- Conference brochure, “World Business Summit on Climate Change,” May 24-26, 2009 (featuring former NRDC Director for Market Innovation Rick Duke at 9) (Att. 19);
- Article, “Is there a ‘proper level’ of compliance with environmental law?” *Trends: ABA Section of Environment, Energy, and Resources Newsletter*, Jan./Feb. 2008 (authored by NRDC Senior Attorney Michael Wall) (Att. 20);
- NRDC Document Bank, <http://docs.nrdc.org/> (Att. 21).

NRDC routinely uses FOIA to obtain information from federal agencies that NRDC legal and scientific experts analyze in order to inform the public about a variety of issues, including energy policy, climate change, wildlife protection, nuclear weapons, pesticides, drinking water safety, and air quality. Some specific examples are provided below:

- (1) In April 2014, NRDC relied on FOIA documents for a report on potentially unsafe chemicals added to food, without the safety oversight of the Food and Drug Administration or the notification of the public. The report, titled *Generally Recognized as Secret: Chemicals Added to Food in the United States*, reveals concerns within the agency about several chemicals used as ingredients in food that manufacturers claim are “generally recognized as safe” (Att. 22). *See also* Kimberly Kindy, “Are secret, dangerous ingredients in your food?” *Wash. Post*, Apr. 7, 2014 (discussing NRDC’s report) (Att. 23).
- (2) NRDC obtained, through FOIA, FDA review documents on the nontherapeutic use of antibiotic additives in livestock and poultry feed. In January 2014, NRDC published a report, titled *Playing Chicken with Antibiotics*, which is based on the documents obtained, and reveals decades of hesitancy on FDA’s part to ensure

the safety of these drug additives (Att. 24). *See also* P.J. Huffstutter and Brian Grow, “Drug critic slams FDA over antibiotic oversight in meat production,” *Reuters*, Jan. 27, 2014 (discussing NRDC’s report) (Att. 25).

- (3) NRDC has used White House documents obtained through FOIA and from other sources to inform the public about EPA’s decision not to protect wildlife and workers from the pesticide atrazine in the face of industry pressure to keep atrazine on the market. *See Still Poisoning the Well: Atrazine Continues to Contaminate Surface Water and Drinking Water in the United States*, <http://www.nrdc.org/health/atrazine/files/atrazinel0.pdf> (Apr. 2010) (update to 2009 report) (Att. 26); *see also* William Souder, “It’s Not Easy Being Green: Are Weed-Killers Turning Frogs Into Hermaphrodites?” *Harper’s Bazaar*, Aug. 1, 2006 (referencing documents obtained and posted online by NRDC) (Att. 27).
- (4) NRDC incorporated information obtained through FOIA into a report, available at <http://www.nrdc.org/wildlife/marine/sound/contents.asp>, on the impacts of military sonar and other industrial noise pollution on marine life. *See Sounding the Depths II: The Rising Toll of Sonar, Shipping and Industrial Ocean Noise on Marine Life* (Nov. 2005) (update to 1999 report) (Att. 28). The report also relied upon and synthesized information from other sources. Since the report’s publication, the sonar issue has continued to attract widespread public attention. *See, e.g.*, “Protest Raised over New Tests of Naval Sonar,” Nat’l Pub. Radio, *All Things Considered*, July 24, 2007 (transcript at Att. 29).
- (5) NRDC scientists have used information obtained through FOIA to publish analyses of the United States’ and other nations’ nuclear weapons programs. In 2004, for example, NRDC scientists incorporated information obtained through FOIA into a feature article on the United States’ plans to deploy a ballistic missile system and the implications for global security. *See* Hans M. Kristensen, Matthew G. McKinzie, and Robert S. Norris, “The Protection Paradox,” *Bulletin of Atomic Scientists*, Mar./Apr. 2004 (Att. 30).
- (6) NRDC obtained through FOIA, and made public, records of the operations of the Bush administration’s Energy Task Force, along with analysis of selected excerpts and links to the administration’s index of withheld documents (Att. 31). NRDC’s efforts cast light on an issue of considerable public interest. *See, e.g.*, Elizabeth Shogren, “Bush Gets One-Two Punch on Energy,” *L.A. Times*, Mar. 28, 2002, at A22 (Att. 32).
- (7) Through FOIA, NRDC obtained a memorandum by ExxonMobil, advocating the replacement of the sitting head of the Intergovernmental Panel on Climate Change, and used the document to help inform the public about what may have been behind the Bush administration’s decision to replace Dr. Robert Watson. *See* NRDC Press Release and attached Exxon memorandum, “Confidential Papers Show Exxon Hand in White House Move to Oust Top Scientist from

International Global Warming Panel,” Apr. 3, 2002 (Att. 33); Elizabeth Shogren, “Charges Fly Over Science Panel Pick,” *L.A. Times*, Apr. 4, 2002, at A19 (Att. 34).

- (8) Through FOIA and other sources, NRDC obtained information on nationwide levels of arsenic in drinking water and used it in a report, *Arsenic and Old Laws* (2000), available in print and online at <http://www.nrdc.org/water/drinking/arsenic/aolinx.asp> (Att. 35). The report guided interested members of the public on how to learn more about arsenic in their own drinking water supplies. *Id.*; see also Steve LaRue, “EPA Aims to Cut Levels of Arsenic in Well Water,” *San Diego Union-Tribune*, June 5, 2000, at B1 (referencing NRDC report) (Att. 36).²

As these examples demonstrate, NRDC has a proven ability to digest, synthesize, and quickly disseminate information gleaned from FOIA requests to a broad audience of interested persons. Therefore, the requested records disclosure is likely to contribute to the public’s understanding of the subject.

4. Significance of the contribution to public understanding

The records requested shed light on a matter of considerable public interest and concern: the transition of power at FDA and the communications between the President-elect’s transition team and FDA staff.

Public understanding of the transition would be significantly enhanced by disclosure of the requested records. Disclosure would help the public to more effectively evaluate the transition and determine whether there have been requests such as the one made to the Department of Energy staff regarding involvement in climate-change issues. Disclosure would also help the public to better understand and evaluate FDA’s response to any such requests. Thus, disclosure here would significantly contribute to the public’s understanding of government operations or activities. 21 C.F.R. § 20.46(b)(4).

B. NRDC Satisfies the Second Fee Waiver Requirement

Disclosure in this case would also satisfy the second prerequisite of a fee waiver request because NRDC does not have any commercial interest that would be furthered by the requested disclosure. 5 U.S.C. § 552(a)(4)(A)(iii); 21 C.F.R. § 20.46(c). NRDC is a not-for-profit organization and does not act as a middleman to resell information obtained under FOIA. “Congress amended FOIA to ensure that it be ‘liberally construed in favor of waivers for noncommercial requesters.’” *Rossotti*, 326 F.3d at 1312 (internal citation omitted); see *Natural Res.*

² There are numerous other examples of national news articles that were based in part on documents NRDC obtained through FOIA. See, e.g., Felicity Barringer, “Science Panel Issues Report on Exposure to Pollutant,” *N.Y. Times*, Jan. 11, 2005 (Att. 37); Katharine Q. Seelye, “Draft of Air Rule is Said to Exempt Many Old Plants,” *N.Y. Times*, Aug. 22, 2003 (Att. 38); Don Van Natta, Jr., “E-Mail Suggests Energy Official Encouraged Lobbyist on Policy,” *N.Y. Times*, Apr. 27, 2002 (Att. 39).

Def. Council v. United States Env'tl. Prot. Agency, 581 F. Supp. 2d 491, 498 (S.D.N.Y. 2008). NRDC wishes to serve the public by reviewing, analyzing, and disclosing newsworthy and presently non-public information about the transition. As noted at Part II.A, any work done by FDA on the transition relates to a matter of considerable public interest and concern. Disclosure of the requested records will contribute significantly to public understanding of the transition.

C. NRDC Is a Media Requester

Even if FDA denies a public interest waiver of all costs and fees, NRDC is a representative of the news media entitled to a reduction of fees under FOIA, 5 U.S.C. § 552(a)(4)(A)(ii), and FDA's FOIA regulations, 21 C.F.R. § 20.45(a)(2). A representative of the news media is "any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience." 5 U.S.C. § 552(a)(4)(A)(ii); *see also Elec. Privacy Info. Ctr. v. Dep't of Def.*, 241 F. Supp. 2d 5, 6, 11-15 (D.D.C. 2003) (a "non-profit public interest organization" qualifies as a representative of the news media under FOIA where it publishes books and newsletters on issues of current interest to the public); Letter from Alexander C. Morris, FOIA Officer, United States Dep't of Energy, to Joshua Berman, NRDC (Feb. 10, 2011) (Att. 40) (granting NRDC media requester status).

NRDC is in part organized and operated to gather and publish or transmit news to the public. As described earlier in this request, NRDC publishes original reporting of environmental news stories on its website, <http://www.nrdc.org>. Previously, NRDC published stories like these in its magazine, *OnEarth*, which has won numerous news media awards, including the Independent Press Award for Best Environmental Coverage and for General Excellence, a Gold Eddie Award for editorial excellence among magazines, and the Phillip D. Reed Memorial Award for Outstanding Writing on the Southern Environment. NRDC also publishes a regular newsletter for its more than one million members and online activists; issues other electronic newsletters, action alerts, public reports and analyses; and maintains free online libraries of these publications. NRDC maintains a significant additional communications presence on the internet through its staff blogs on <http://www.nrdc.org>, which are updated regularly and feature writing about current environmental issues, through daily news messaging on "Twitter" and "Facebook," and through content distributed to outlets such as Medium. *See* OPEN Government Act of 2007, Pub. L. No. 110-175, § 3, 121 Stat. 2524 (2007) (codified at 5 U.S.C. § 552(a)(4)(A)(ii)) (clarifying that "as methods of news delivery evolve . . . such alternative media shall be considered to be news-media entities"). The aforementioned publications and media sources routinely include information about current events of interest to the readership and the public. To publish and transmit this news content, NRDC employs more than fifty staff members dedicated full-time to communications with the public, including accomplished journalists and editors. These staff members rely on information acquired under FOIA and through other means. Public interest organizations meeting the requirements "are regularly

granted news representative status.” *Serv. Women’s Action Network v. Dep’t of Def.*, 888 F. Supp. 2d 282, 287-88 (D. Conn. 2012) (according media requester status to the ACLU).³

Information obtained as a result of this request will, if appropriately newsworthy, be synthesized with information from other sources and used by NRDC to create and disseminate unique articles, reports, analyses, blogs, tweets, emails, and/or other distinct informational works through one or more of NRDC’s publications or other suitable media channels. NRDC staff gather information from a variety of sources—including documents provided pursuant to FOIA requests—to write original articles and reports that are featured on its website, in its newsletters and blogs, and on other media outlets. *See Cause of Action v. Fed. Trade Comm’n*, 961 F. Supp. 2d 142, 163 (D.D.C. 2013) (explaining that an organization can qualify for media-requester status if it “distributes work to an audience and is especially organized around doing so”). NRDC seeks the requested records to aid its own news-disseminating activities by obtaining, analyzing, and distributing information likely to contribute significantly to public understanding, not to resell the information to other media organizations.

III. Willingness to Pay Fees Under Protest

Please provide the records requested above regardless of your fee waiver decision. In order to expedite a response, NRDC will, if necessary and under protest, pay fees in accordance with FDA’s FOIA regulations for all or a portion of the requested records. *See* 21 C.F.R. § 20.45. Please contact me before doing anything that would cause the fee to exceed \$250. NRDC reserves its rights to seek administrative or judicial review of any fee waiver denial.

IV. Conclusion

Please email or (if it is not possible to email) mail the requested records to me at the NRDC office address listed below. Please send them on a rolling basis; FDA’s search for—or deliberations concerning—certain records should not delay the production of others that FDA has already retrieved and elected to produce. *See generally* 21 C.F.R. § 20.22, 20.43. If FDA concludes that any of the records requested here are publicly available, please let me know.

Please do not hesitate to call or email with questions. Thank you.

Sincerely,

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Enclosures (sent via FOIA Online): Attachments 1 through 42 (single .pdf file)

³ To be a representative of the news media, an organization need not *exclusively* perform news gathering functions. If that were required, major news and entertainment entities like the National Broadcasting Company (NBC) would not qualify as representatives of the news media.